

Message

From: Romano, Anthony [/O=CAH/OU=CARDINAL HEALTH/CN=RECIPIENTS/CN=ANTHONY.ROMANO]
Sent: 5/6/2008 6:01:38 PM
To: Mone, Michael [/O=CAH/OU=CARDINAL HEALTH/CN=RECIPIENTS/CN=MICHAEL.MONE]
Subject: Anti-Diversion and SOM Training
Attachments: Anti-Diversion_SOM_Training.zip

Michael,

Attached is a zip file that has the 2 videos and presentation from our February training session. Let me know if you have any issues opening the videos.

Thanks!

Tony Romano
Director, Sales Training
HealthCare Supply Chain Services-Pharmaceutical

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WELCOME

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Kick-Off

George Barrett

Cardinal Health, HSCS Vice Chairman and CEO

Jeff Henderson

Cardinal Health, CFO

Mark Hartman

Cardinal Health, SVP Supply Chain Integrity

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Housekeeping

- Company confidential
- Breaks – Restrooms
- Please turn off Blackberries and Cell Phones
- Interactive session – SPEAK UP!



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Training objectives

- **Understand the mission of the Drug Enforcement Administration (“DEA”) and Cardinal Health’s obligations under the Controlled Substances Act and accompanying regulations**
- **Understand the changing regulatory atmosphere**
- **Recall and understand DEA handling, record keeping and reporting requirements**
- **Understand Cardinal Health's enhanced Suspicious Order Monitoring (SOM) Program**



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Superbowl Sunday Clips

- Video Clips



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Diversion – An Overview

Jodi Avergun

Special Counsel, Cadwalader, Wickersham & Taft, Washington, D.C.

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Drug Enforcement Administration (DEA)

- **History and Operations**
 - Criminal
 - Regulatory
 - Intelligence
- **Management/structure:**
 - Central control in HQ – part of DEA operations division
 - 400 diversion investigators in the world. Over 1 million registrants for them to both service and investigate.
 - Choke point view – all prescription drugs go through wholesale distributors
- **Developments in regulatory controls**
 - Controlled substances
 - Suspicious order monitoring
 - SEPT / 06 Letter
 - FEB / 07 Letter
 - DEC / 07 Letter
 - Chemicals – Methamphetamine as focus



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DEA – Industry Meetings

- **Beginning in mid 2005, DEA began calling in distributors to educate them about the issue of prescription drug diversion and specifically to highlight concerns about Internet pharmacy**
- **General presentation:**
 - The law
 - Trends
 - Problematic customers identified



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DEA Guidance – Feb/Sept 07

- Reporting suspicious orders to DEA does **NOT** relieve a distributor of the responsibility to maintain effective controls to prevent diversion.
- DEA official told this to industry conference in September 2007 (“If you report suspicious orders, yet fill them You are **failing** to maintain effective controls to prevent diversion”).
- DEA provided warning letter to all distributors in early 2007.



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Current Issue – What is driving all this?

- Non-medical use of pharmaceutical products is now greater than the abuse of cocaine, hallucinogens and inhalants. Among adults 26 or older, 6.3 percent reported non-medical use of prescription medicines in 2005. In children 12 or older, 2.2 million reported non-medical use of prescription medicines, mainly pain relievers and tranquilizing medicines.

Source

http://www.goodmedicinebadbehavior.org/explore/history_of_prescription_drugs.html

- One of 20 high school seniors admit to abusing prescription pain killers such as vicodin and oxycontin

Source: www.monitoringthefuture.org

- In order to bring attention to the problem of non-medical use of prescription medicines, the United States Congress declares each August as "National Medicine Abuse Awareness Month."



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President Bush and National Drug Control Strategy

- **President Bush December 11, 2007 White House press conference:**
“In 2002, I committed our nation to an ambitious goal: to cut drug use amongst young people by 25 percent over a five-year period”. John Walters agreed with that goal. He's been in charge of leading an effort to achieve that goal. This strategy has had promising results. This morning I was briefed on the latest Monitoring the Future study, which tracks drug use amongst America's youth. It reports that since 2001, the overall use of illicit drugs by young people has dropped by 24 percent. Marijuana use fell by 25 percent, steroid use by a third, and the use of ecstasy by 54 percent. The most encouraging statistic relates to the use of methamphetamine, which has plummeted by an impressive 64 percent since 2001.
- **One exception to this trend is a rise in the abuse of certain prescription pain killers. This is troubling, and we're going to continue to confront the challenge**
- **<http://www.whitehouse.gov/news/releases/2007/12/20071211-4.html>**



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How dangerous is it to abuse prescription drugs?

- **Perception of safety because it is medicine**
- **Less of a stigma, because of the ease of access**
- **No need to go to dark alleys**

But....



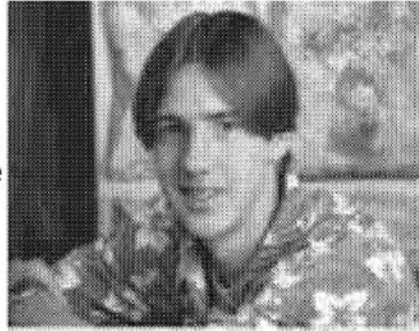
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Ryan Haight

Ryan Thomas Haight overdosed and died on February 12, 2001 on narcotics that he had easily purchased on the Internet. A medical doctor on the Internet that he never saw prescribed them, an Internet pharmacy mailed them to his home. He was only 17 when he purchased them, he was only 18 when he died. It is too simple to get dangerous prescription drugs on the Internet. It is too easy for our youths to get information about drugs and to find out how and where to get them.



<http://www.ryanscause.org/index.html>



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Jason Surks

Jason Surks was nineteen when he died from an overdose of Xanax™. After his death, his parents discovered that he had been ordering controlled substances from an Internet pharmacy in Mexico. Jason had been buying the anti-anxiety medication along with the painkiller OxyContin on the Internet, unbeknown to his parents. Ironies— Jason was a pre-pharmacy major and his mom spent her entire career working at a drug and alcohol abuse counseling center.

Source: www.justthinktwice.com



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The Perfect Storm

- **Presidential mandate to cut drug use – yet one category is rising**
- **Dwindling DEA resources**
- **Proliferation of Internet**
- **Congressional interest in issue – children dying, tremendous costs to society**
- **Application of traditional principles of enforcement to industry**



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Responsibility

- **Recognition and prevention**

- Everyone's responsibility
- Sales force – you are the boots on the ground and the front line of defense
- Vault and Cage workers in DC – you provide a critical second look and can identify unusual orders based on your experience with customers
- Compliance workers in the DCs – you monitor all and are the key connection between the sales force and the operations teams and need to know what is going on on both sides of the house
 - You are also the key ingredient to an effective relationship with your local DEA office
- Corporate QRA

EVERYONE HAS A PIECE OF THIS RESPONSIBILITY



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Diversion concerns

- Pharmaceutical drugs
 - Hydrocodone
 - Oxycodone
 - Dilaudid (Hydromorphone)
 - Methadone
 - Alprazolam
 - Diazepam
 - Phentermine



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Some Drugs of Concern Vicodin™ and other hydrocodone products



Vicodin™ and other hydrocodone products: Hydrocodone is a semi-synthetic opioid similar in effects to morphine. Vicodin™ is hydrocodone mixed with acetaminophen. Hydrocodone products, when abused, can lead to dependence, tolerance, and addiction. Vicodin™ is one of the most frequently prescribed medications for pain. Other products include Vicoprofen™, Tussionex™, and Lortab Pure hydrocodone is in schedule II. Hydrocodone combination products are in schedules III and V.

<http://www.justthinktwice.com/drugfacts/painkillers.cfm>



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Tramadol



- **ULTRAM™ (tramadol hydrochloride)** and **ULTRACET™** (tramadol with acetaminophen) are prescription medications indicated for the management of moderate to moderately severe pain. Side effects include: dizziness, drowsiness, or headache; nervousness, tremor, or anxiety; nausea, vomiting, constipation, or diarrhea; or itching, dry mouth, or sweating.
- Tramadol is habit forming. Physical and/or psychological dependence can occur, and withdrawal effects are possible if the medication is stopped suddenly after prolonged or high-dose treatment
- NOTE: not currently scheduled

<http://www.justthinktwice.com/drugfacts/painkillers.cfm>



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Fentanyl



- **FENTANYL™** is extensively used for anesthesia and analgesia.
- Duragesic™ is a fentanyl transdermal patch used in chronic pain management, and Actiq is a solid formulation of fentanyl citrate on a stick that dissolves slowly in the mouth for transmucosal absorption.
- Illicit use of pharmaceutical fentanyl first appeared in the mid-1970's in the medical community. To date, over 12 different analogues of fentanyl have been produced clandestinely and identified in the U.S. drug traffic.
- The biological effects are indistinguishable from those of heroin, with the exception that the fentanyls may be hundreds of times more potent.
- Fentanyls are most commonly used by intravenous administration, but like heroin, they may also be smoked or snorted.

<http://www.justthinktwice.com/drugfacts/painkillers.cfm>

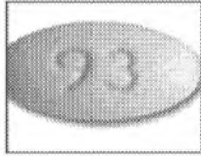


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Oxycodone



- **OxyContin™ and other oxycodone products:** Oxycodone is used as an analgesic and is formulated into numerous pharmaceuticals including OxyContin™ (a controlled-release product) and with aspirin (Percodan™) or with acetaminophen (Percocet™).
- These drugs are prescribed for pain relief. They all require a doctor's prescription and are prescribed for moderate to severe pain.
- Oxycodone is in Schedule II

<http://www.justthinktwice.com/drugfacts/painkillers.cfm>



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Alprazolam and other benzodiazepines

- **Xanax™** (alprazolam) is from the benzodiazepine family of depressants. It is used to treat insomnia in patients with daytime anxiety or as an anticonvulsant. Alprazolam and diazepam are the two most frequently encountered benzodiazepines on the illicit market.
- **Valium™ (diazepam)** is from the benzodiazepine family of depressants. It is utilized to treat insomnia in patients with daytime anxiety or as an anticonvulsant. It is among the most widely prescribed medications in the United States. Abuse is frequently associated with adolescents and young adults who take the drug to get high. Concurrent use of alcohol or other depressants with Valium™ can be life-threatening. Abuse of benzodiazepines is particularly high among heroin and cocaine abusers.
- Valium™ and Xanax™ are in schedule IV.
- <http://www.justthinktwice.com/drugfacts/prescription.cfm>



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Phentermine

- A number of drugs have been developed and marketed to replace amphetamines as appetite suppressants. These anorectic drugs include benzphetamine (Didrex®), diethylpropion (Tenuate®, Tepanil®), mazindol (Sanorex®, Mazanor®), phendimetrazine (Bontril®, Prelu-27®), and phentermine (Ionamin®, Fastin®, Adipex®). These substances are in Schedule III or IV of the CSA and produce some amphetamine-like effects. Of these diet pills, phentermine is the most widely prescribed and most frequently encountered on the illicit market. Two Schedule IV anorectics often used in combination with phentermine (phen-fen combo), fenfluramine and dexfenfluramine, were removed from the U.S. market due to heart valve problems

http://www.usdoj.gov/dea/concern/anorectic_drugs.html



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Registrant Responsibilities Overview

Ron W. Buzzeo

Chief Regulatory Officer, Compliance Solutions Powered by BuzzeoPDMA,
Cegedim Dendrite, Richmond, VA

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The changing landscape

Yesterday vs. today—what is driving the change?

- **Increased federal oversight**
 - DEA
 - Political – Executive and Congressional Branch
 - FDA
 - PDMA
 - Counterfeit/outdates/damaged
- **Increased state oversight**
 - Regulatory boards
 - Drug distributor licensing
 - Drug pedigree
 - Gift reporting
 - Theft and loss reporting
 - Counterfeit/outdates/damaged
 - Political



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Methods of diversion

- Methods of diversion
 - Internet
 - Indiscriminate prescribing
 - Forged prescriptions
 - Doctor shopping
 - Pain clinics
 - Employee and non-employee thefts
 - In-transit losses
 - Financiers
 - Excessive orders / distribution
 - Sales



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Controlled substances act

- Passed in 1970, effective in 1971
- Established the concept of a “controlled substance” which included both opioids/opiates and psychotropic substances
- Placed within the Department of Justice
- Established a “closed system”
- Only legally registered persons may possess controlled substances
- Records must be maintained when controlled substances are transferred from one registrant to another
- Provide adequate supply for medical requirements



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Controlled substances

- **A drug or other substance, or immediate precursor, included in schedules I, II, III, IV or V**

Opioids/Opiates

Depressants

Sedatives

Hallucinogenics

Stimulants

Anabolic

- **Schedule I**
 - No legitimate medical use – Marijuana, Heroin, LSD
- **Schedule II**
 - High abuse, limited medical use, Morphine, Oxycodone, Amphetamines, Methylphenidate, Secobarbital
- **Schedule III**
 - Hydrocodone and Codeine combination
- **Schedule IV**
 - Diazepam, Lorazepam
- **Schedule V**
 - Cough preparations with Codeine



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Controlled substances act–continued

- Drug schedules
- Registration
- Security
- Quotas
- Records/reports
- Order forms
- Prescriptions
- Import
- Export



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Common Industry Regulatory Violations



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Registrations

Manufacturing (Schedule I - V)	Distribution (Schedule I - V)	Dispensing/ instruction (Schedule II - V)
Chemical analysis (Schedule I - V)	Research (Schedule I - V)	Import (Schedule I - V)
Export (Schedule I - V)	NTP (Schedule II - V)	



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Separate sheet on share positions? Overall market size?

If not, mention share positions, market sizes and market growth rates vs. our growth rates. Discuss drivers of success and the advantages of our market position(s) and products.

Registration– Issues

- Signature
 - Un-authorized person
- Power of attorney
 - Failure to forward to the DEA
- Coincident activities
 - Researcher – product development



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Distribution center records and reports



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Diversion concerns–DC

- Unsecured drugs in the receiving/distribution areas
- Poor inventory controls for drugs awaiting destruction
- Access to computer programs to change “on hand” balances
- Inventory adjustments
- Use of trash cans/receptacles for diversion
- Inadequate use of cameras
- Lack of access controls
- Personal belongings



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General requirements / violations

- Controlled substance records not available for inspection
 - May request central recordkeeping for some records
 - Records must be maintained for two years
- Lack date of activity
- Schedule II records not maintained separate from other records
- Schedule III, IV and V records not “readily retrievable”



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Controlled substance requirements– Records / violations

- Schedule II
 - DEA form 222
 - Entries not complete
 - Receiving and distribution record
 - Lack date of activity
 - Lack DEA Registration number
 - Supplier / customer name, address and DEA registration number, actual date of receipt / distribution, drug name, strength, dosage form, quantity and number of commercial containers
- Schedule III, IV AND V
 - Receiving and distribution record
 - Lack date of activity
 - Lack DEA Registration number



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Controlled substance requirements– Reports / violations

- DEA 106
 - Theft and significant losses
 - Failure to report or not timely
 - Failure to report significant losses
 - All thefts must be reported within one business day, in writing, to be followed by a DEA 106
 - Only significant losses are to be reported on a DEA 106
 - » Establish significant loss threshold / SOP
 - In transit losses to be reported by the supplier
- DEA 41
 - Disposal without approval
- ARCOS
 - Failure to correct errors provided by the DEA
 - Date of activity (shipment / receipt)



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Controlled substance requirements– Reports

- Suspicious order monitoring (SOM)
 - Excessive quantities
 - Unusual frequencies
 - Unusual size
 - Orders deviating substantially from a normal pattern
- Reporting
- Ship – Don't ship



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Inventory and inventory adjustments



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Controlled substance inventory / violations

- Inventory
 - Schedule II not separate from Schedule III, IV and V
 - Does not include all controlled substances, such as
 - Outdates
 - Held for disposal
 - Damaged
 - Not conducted as of the open or close of business
 - Not an exact account



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Inventory adjustments / automatic

- Need for documentation, review and approval prior to an inventory adjustment
 - Conduct a review/investigation
 - Records must document
 - The investigation conducted / DEA-type accountability
 - The identity and quantity of the drugs
 - Ensure that the number of employees is limited, and a report is completed prior to the adjustment
 - Thefts and significant losses require a report to the DEA upon discovery, within one business day, in writing



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Security



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Controlled substance security / Issues

- **Schedule II**
 - Vault
 - Safe
 - Un-limited and lack of controlled access
 - Lack of designated employee(s)
- **Schedule III, IV and V**
 - Cage
 - Un-limited and lack of controlled access
 - Lack of designated employee(s)
- **Cameras – not required but recommended**
- **Alarms – Not sufficient, lack coverage**
- **Shipping containers – identify a controlled substance**



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DEA accountability

What records reviewed.

What the Process is.



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DEA Accountability chart

[illegible]

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Pharmacy dispensing



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Controlled substances pharmacy dispensing

- **Pharmacist responsibility**
 - Legal responsibility – state and federal requirements for dispensing CS
 - Personal responsibility – protect your practice from becoming an easy target for drug diversion
 - Constant vigilance against forged and altered prescriptions
- **Fraudulent prescriptions**
 - Alteration of prescriptions
 - Forged prescriptions
 - Non-medical



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Controlled substances pharmacy dispensing

- Possible indication of non-medical prescribing
 - Prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the area
 - The patient appears to be returning too frequently
 - The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time
 - Patient appears presenting prescriptions written in the names of other people
 - A number of people appear simultaneously, or over a short time, all bearing similar prescriptions from the same physician
 - Numerous “strangers,” people who are not regular patrons or residents of the community, suddenly show up with prescriptions from the same physician
 - **Long term use of Schedule III narcotics**



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Controlled substances pharmacy dispensing

- Characteristics of forged prescriptions
 - Prescription looks too good – too legible
 - Quantities, directions or doses differ from usual medical usage
 - Prescription does not comply with the acceptable standard abbreviations
 - Prescriptions appears to be photocopied
 - Directions written in full with no abbreviations



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Controlled substances pharmacy dispensing

- Prevention techniques
 - Know the prescriber and signature
 - Know the prescriber's DEA registration number
 - Know the patient
 - Check the date on the prescription order. Has it been presented in a reasonable length of time?
 - Drugs prescribed
 - Discuss treatment with physician
 - Drug testing
 - Patient and physician contracts
 - Physician and pharmacy contracts



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DC Diversion Prevention



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Recent DEA Guidance

- On December 27, 2007, Joe Rannazissi, Assistant Administrator for Diversion Control, wrote to all wholesalers and manufacturers: He stated:
 - In addition to the obligations to maintain effective controls against diversion, they must also **REPORT** suspicious orders of controlled substances **WHEN DISCOVERED**
 - Monthly report after the fact – such as our Ingredient Limit Report (ILR) – **DOES NOT** satisfy this obligation.
- Other obligations in letter:
 - Independent analysis of suspicious orders prior to completing sale
 - Reiterates definition of suspicious as those that deviate substantially from normal patterns, and orders of unusual frequency. not exclusive definition.
 - The size of an order alone, whether or not it deviates is enough to trigger registrant's obligation to report.
 - Must compare not only within customer but to patterns within your entire customer base and throughout the relevant segment of the regulated industry – imposes obligation to understand industry
 - Must clearly characterize order as suspicious. Regular reporting of "excessive purchases" is not deemed to be adequate suspicious order monitoring



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Techniques to prevent diversion in the Field

- Prevention techniques
 - Know the pharmacy
 - Location
 - Physicians and clinics in area
 - Types
 - Types of customers
 - Loitering
 - Ordering pattern
 - Types of drugs
 - Monitor all orders
 - Frequency
 - Size
 - Pattern
 - Check the date on the order - Has it been a reasonable length of time



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DEA Internet Policy

- Usual course of professional practice
 - Patient with a medical complaint
 - History
 - Physical examination
 - Nexus between complaint/history/exam and drug prescribed



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DEA Internet Policy (cont'd)

- Prescriptions can only be issued by a doctor acting in the usual course of professional practice
- Prescription not issued in the usual course of professional practice is not valid
- Drugs dispensed pursuant to invalid prescriptions are not for legitimate medical purpose, the drugs are diverted



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How to assess if your customer is a problematic Internet or a questionable pharmacy

- Looking for signs of Internet activity (shipping supplies, lack of walk-in customers, etc.) or filling prescriptions from questionable “pain clinics” or other questionable physicians.
- Red flags would include:
 - Pharmacies with minimal or no front end merchandise.
 - Pharmacies with little or no walk-in business.
 - Pharmacies with primarily cash customers.
 - Pharmacies ordering a high percentage of controlled substances relative to non-controlled substances.
 - Pharmacies ordering excessive quantities of a limited variety of controlled substances.
 - Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled?
 - Does the pharmacy solicit buyers of controlled substances via the Internet?



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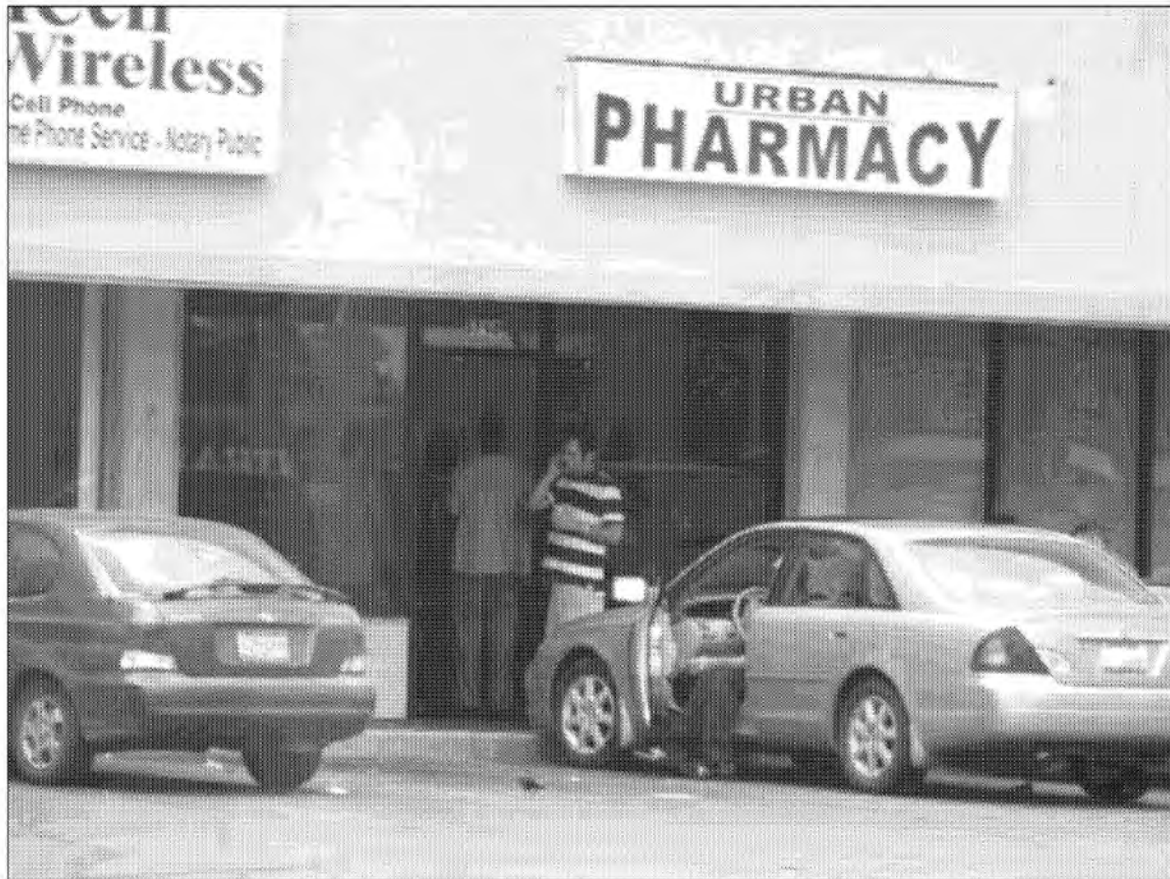


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Southwood Pharmaceuticals, Inc.

- Customer – Medipharma Pharmacy 99% of purchases were Controlled Substances

Month	DU/hydrocodone
Dec 06	817,010
Jan 06	939,340
Feb 06	1,142,250
Mar 06	1,071,450
April 06	703,550
May 06	808,500
June 06	1,142,000
July 06	800,340
Aug 06	1,246,560
Sept 06	1,450,380
Oct 06	1,009,320



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Southwood Pharmaceuticals, Inc. - cont'd

- Avee Pharmacy – Admitted Internet pharmacy – 100% controlled substance sales

Month	DU
Dec 05	346,140
Jan 06	859,860
Feb 06	0
Mar 06	912,190
April 06	76,190
May 06	212,000
June 06	442,800
July 06	94,000
Aug 06	506,430
Sep 06	695,800
October 06	537,900
Nov 06	2,111,800



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Horen's Drug Store

- Cited as Auburn's largest hydrocodone customer for 2007
- Total purchases in 7 month period were over 600,000 dosage units
- Some monthly purchases exceeded 100,000 dosage units month
- Horen's Drug Store was mentioned by name on an Internet chat room as a good source for illegal prescriptions



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Swedesboro Customers

Pharmacy	Months of Distribution	Monthly Avg
Medi-Pharm	4	155,007
DRM Enterprises	22	42,254
Jen-Mar	11	2,766 (1 st 3 mos) 42,175(last 8 mos)
Armenia Pharmacy	12	1,900 (1 st 6 mos) 20,000 (last 6 mos)
National Pharmacy	9	73,311
Parulmed	20	23,420
QRG	5	242,640
RKR Holdings	13	57,000
United Prescrip Services	4	287,025
Satellite Drug and Pharmacy	19	375 (1 st 4 mos) 69,500 (last 15 mos)



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RT

Problems / Case Scenarios Discussions



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Scenario 1

- A pharmacy orders large quantities of controlled substances and non-controlled substances
- The pharmacy has a pain clinic nearby
 - All the patients have the same prescribed hydrocodone combination product
- Young clientele
- Waiting in line
- Loitering outside



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Scenario 1 - Discussion

What would you do?



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Scenario 2

- No outside sign
- Open 24 hours per week
- 75% of Prescriptions are for Controlled Substances (CS)
- 50% Cash
- Pain clinics in vicinity
 - All the patients have the same prescribed hydrocodone combination product
- Apparent lack of Non-CS
- Patients enter with ID in hand
- 3 windows for service (one for non-cs and two for cs)
- Fills Prescriptions for patients of near-by state
- 15 people entered the pharmacy (late 20s early 30s) with prescriptions for Lorcet 10/325. Pharmacy out-of-stock, sent patients back to physicians for new prescription for strength in stock



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Scenario 2 - Discussion

What would you do?



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Scenario 3

- 35% of Prescriptions are for CS
- Located on ground floor of a medical building that houses approx 60 physician's offices
- Security guard on duty during business hours
- Due to Cardinal restrictions, pharmacist has referred two physicians to the DEA for possible excessive prescribing who were described as HIV and/or pain management practitioners. The pharmacist is also forwarding letters to 200 to 300 HIV patients that she will no longer be able to fill OxyContin and Dilaudid prescriptions
- Only about 5% of prescriptions are written by physicians located in the medical building and/or Hospital which is located across the street.



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Scenario 3 - Discussion

What would you do?



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Scenario 4

- Fill approx 8% of prescriptions from a boarder state
- The filling of prescriptions from patients of this state was larger, but discontinued filling prescriptions from a pain clinic in October, 07 as they did not like the patients.
 - Notified Board of Pharmacy of their decision.
- 4% of business is attributed to Hospice patients
- Insurance (35%)
- Medicare/Medicaid (50%)
- Cash (15%)
- Two physicians and a dentist in the same building
- Numerous physicians and clinics within 10 minute drive. Also 10 minutes from another large town
- Approx 15 – 18% of Prescriptions are for CS



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Scenario 4 - Discussion

What would you do?



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Scenario 5

- Fills out-of-state prescriptions if patient is visiting
- Ships hormone replacement compounded prescriptions for testosterone, progesterone to patients in several states on occasion
- No apparent out-of-state licenses
- 20% of Prescriptions are for CS
- 20% cash
- Pain management and hand surgery clinics located in vicinity
- Located in a complex of medical offices
- Not far from a Hospital and a Neurological Center
- Pharmacy provides supplies to physician's offices
- High dispensing of Schedule II provided by owner
- Pharmacy is mentioned in Federal Register/Vol. 69, No. 48/Thursday, March 11, 2004 – as filling prescriptions written by a physician after the physician reviewed on-line questionnaires
- Evidence of Internet activity until 3/3/06



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Scenario 5 - Discussion

What would you do?



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Scenario 6

- Pharmacy open one month
- Owner of another pharmacy
- 10% cash
- Pain Management Clinic next door which writes large prescription orders.
- Primary physician at clinic received letter of reprimand from the Medical Board for failure to supervise a PA, failure to File a Notice of Supervision and failure to obtain Board approval for prescribing Schedule II and II controlled substances by a PA.



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Scenario 6- Discussion

What would you do?



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Scenario 7

- 100% of Prescriptions are for CS
- 100% cash business
- Schedule III, IV and V controlled substances
- Fills prescriptions from another state - located on border
- 100% Pain management
- Located across street from Pain Clinic



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Scenario 7 - Discussion

What would you do?



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Scenario 8

- 30 to 40% of Prescriptions are for CS
- 60% of CS prescriptions require cash
- Co-located with BBQ fast food and ice cream store
- Observed no foot traffic
- Mostly un-occupied strip mall in a run down section of town



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Scenario 8 - Discussion

What would you do?



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Suspicious Order Monitoring

Michael A. Mone, R.Ph, JD, FAPhA
Cardinal Health, VP Anti-Diversion



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Objectives

- Understand the obligations of Cardinal Health for supply chain integrity
- Understand the components of the Cardinal Health Suspicious Order Monitoring Program
- Explain the Cardinal Health Suspicious Order Monitoring Program to internal and external customers
- Raise awareness of Cardinal Health employees of their role in Anti-Diversion of controlled substances



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Anti-Diversion... is *everyone's* responsibility.

Prescription drug diversion is a societal problem to be addressed by a societal solution involving all participants in the prescription drug supply chain: from manufacturer to patient with the collaboration and cooperation of regulatory bodies on the state and federal levels.



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Suspicious Order Monitoring

- SOM = Suspicious Order Monitoring
 - Suspicious
 - Order
 - Monitoring
- Why do something?
 - Program developed to meet Cardinal Health's regulatory obligations to **identify, block and report** the intent to order controlled substances that may pose a risk for potential diversion.
 - Enhancement of our efforts in the past



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Suspicious Order Monitoring

- Why now?
 - Drug diversion of controlled substances increasing
 - Teenage access to controlled substances – death and serious injury
 - January 24, 2008 newsday.com headline
 - Mt. Sinai pharmacist charged in Vicodin scheme
 - January 26, 2008 Charleston Daily Mail
 - Actor's death renews discussion on prescription drug abuse
 - February 1, 2008 WBAY Channel 2 Green Bay
 - Two arrested in investigation of Oshkosh woman's death
 - Xanax



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BS

Thoughts on SOM

- The system must create a strategic move in the marketplace for Cardinal Health and our customers that will enable us to provide our customers with a measure of quality performance in their operations.



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Thoughts on SOM

- The system is designed to be used in conjunction with other Cardinal Health products and services to have **value** to our customers and not be viewed as a regulatory impediment to their business performance.



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Thoughts on SOM

- SOM with Cardinal Inventory Manager (CIM) and other products and services offers our customers and Cardinal Health a reasonable assurance of a legally and regulatory valid business performance.



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Suspicious Order Monitoring

- Components
 - Our people
 - Know your customer
 - New Pharmacy Customer Questionnaire
 - IT Component
 - Thresholds - customized
 - Account evaluation
 - Communication
 - Across all Cardinal Health business units
 - All roles involved in SOM



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Know Your Customer Program **New Pharmacy Questionnaire**

- Required as part of account approval process for all new retail independent and wholesaler accounts.
- Pharmacy Business Consultant is responsible for filling out the questionnaire and submitting it to Corporate QRA for approval.
- Information should be obtained from the pharmacy owner and signed by the owner.
- The Pharmacy Business Consultant is the first contact for Cardinal Health in preventing diversion.
- The questionnaire must be taken seriously and must be filled out thoroughly and accurately.



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What are “Red Flags”

- Looking for signs of Internet activity (shipping supplies, lack of walk-in customers, etc.) and filling prescriptions from questionable “pain clinics”. Red flags would include
 - Pharmacies with minimal or no front end merchandise.
 - Pharmacies with little or no walk-in business.
 - Pharmacies with primarily cash customers.
 - Pharmacies ordering a high percentage of controlled substances relative to non-controlled substances.
 - Pharmacies ordering excessive quantities of a limited variety of controlled substances.
 - Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled?
 - Does the pharmacy solicit buyers of controlled substances via the Internet?



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BT

Contents of the New Pharmacy Questionnaire

- General Information about Pharmacy, its owner and its pharmacist in charge
 - Goal is to make sure that the pharmacy is registered with the DEA, those behind the pharmacy are licensed and can easily be contacted – provides for accountability.
 - Make sure that a clear picture is formed regarding all other pharmacies owned by the same owner.
 - Questionnaire asks for compliance history – has the license ever been revoked? This could be a red flag and might indicate a lack of commitment to compliance by the pharmacy's owner or operator.



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P2

New Pharmacy Questionnaire (con't)

- Other suppliers
 - It is important to understand whether the customer has other suppliers so that you can make a determination, where possible, of the total amount of controlled substances the customer will be obtaining.
 - While it might be difficult to ascertain information about other suppliers, you should at least document your efforts to try to obtain that information. If your customer will not tell you, you should note that on the form.
 - You should reassure your customer that you are not seeking that information for competitive advantage, but to try to comply with enhanced anti-diversion standards being imposed by DEA.



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PH

New Pharmacy Questionnaire (con't)

- The Pharmacy's Customers
 - Certain types of customers might raise concerns for the regulators or might, on the other hand, justify a seemingly excessive order. Context is important.
 - For example, if your customer services a nursing home, an oncology center, or a hospital, that customer would probably have larger orders than a customer serving individuals who walk in – there are simply more patients to service.
 - Similarly, if a pharmacy fills prescriptions exclusively for individual walk in customers with little to no phoned in prescriptions, that might be suspect as well.



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PH

New Pharmacy Questionnaire (con't)

- **Out of State Shipments or Out of State Customers**

Why is this important?

- In general, it should not be necessary for a patient of an independent pharmacy to go outside his state of residence to fill a prescription. (Border cities are an exception.)
- The further away a pharmacy is from the patients for which it fills prescriptions, the more suspect it is. The PBC should inquire further as to why the pharmacy's customers are located in different states.
- Large amounts of shipments out of state, coupled with little walk-in traffic, is another red flag.



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BS

New Pharmacy Questionnaire (con't)

- Pharmacy's Affiliation with Internet website
 - A critical red flag. DEA has found in recent years that many pharmacies supply controlled substances over the Internet through on-line orders that might not have been the result of a valid doctor-patient relationship.
 - If you are dealing with a pharmacy that fills on-line orders, you must scrutinize more carefully.
 - A factor that you must consider is, what percentage of total Rx sales are generated from a website. The greater the percentage, the more potentially risky the sale.
 - Also need to consider type of on-line ordering. Is it the customer's own website that allows new prescription requests? Or is it the pharmacy filling orders for another Internet website?



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PH

New Pharmacy Questionnaire (con't)

- Method of Payment
 - The DEA has indicated that if a large percentage of a pharmacy's total sales are for cash sales, this is a potential red flag.
 - Be careful to understand the percentage breakdown of cash vs insurance payments or Medicare/Medicaid reimbursements. Be sure to ask the pharmacist why the breakdowns are the way they are. Is the neighborhood in which the pharmacy is located an area in which most residents receive public assistance? Would you expect more Medicaid than cash payments in such a case?
 - Are sales of other products at the pharmacy paid for in the same manner as controlled substances?



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New Pharmacy Questionnaire (con't)

- Pharmaceutical Needs
 - DEA has indicated that a large percentage of controlled substance orders compared to total orders might be a red flag for diversion occurring.
 - You should try to ascertain the expected product mix a customer anticipates ordering.
 - If a pharmacy intends to purchase only controlled substances or a high percentage of controlled substances, an explanation must be provided and noted on the questionnaire.



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New Pharmacy Questionnaire - data

- Component of know your customer
- New account
 - New store
 - Existing store, new to Cardinal Health
- Evaluation is customer specific
 - New store – small category
 - Existing store – 12 month total dollar purchases from prior wholesaler and if computer can provide a breakdown of the monthly purchases of controlled substances



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New Pharmacy Questionnaire

- Key information
 - Ownership
 - History of purchases
 - Power of Attorney
 - Location
 - Business model
 - Compounding
 - LTC
 - Hospice



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Pharmacy DEA Compliance Agreement

- Required to be signed by the Pharmacy **Owner**.
- Other distributors ask for similar certifications.
- Purpose is to have the pharmacy agree that they will not fill prescriptions that are not issued for a legitimate medical purpose and in the normal course of professional practice.
 - This protects Cardinal Health. In most instances, we are not in a position to investigate the individual prescriptions filled by our customers. Therefore, we ask them to certify that they are not filling prescriptions that do not appear to be issued for a legitimate medical purpose in the normal course of professional practice.
- The agreement also asks the customer to be alert for “red flags” that may indicate suspicious prescriptions.



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Our People

- Know your customer training
 - On-line training in December 2007
 - Documentation
 - Application
 - Sea-change in relationship
- Validation of customer purchases
- Focus is accountability and knowledge
- Awareness of business practices of our customers
- Build relationships and offer tools to assist customers like CIM



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10/08

The Internet

- Internet – What is it?
 - A communications medium
 - A business platform
 - A worldwide, publicly accessible network of interconnected computer networks that transmit data by packet switching using the standard Internet Protocol (IP).
- What defines a legitimate use of the Internet in pharmacy commerce?



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10/11

The Internet

- DEA policy can be found at:
 - <http://www.deadiversion.usdoj.gov/faq/internetpurch.htm>
- Essentially: no valid prescriber-patient relationship = no valid “prescription” = can’t dispense pursuant to the “prescription”
- Prescription must be for a legitimate medical purpose
- Historically, validity of prescriber-patient relationship was founded in state law
- Internet has not changed the analysis, just jurisdiction and enforcement
- Administrative, civil and criminal prosecutions
- How to address the epiphany?



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Diversion

- Multiple methodologies
- Internal
- External
 - Our customers
 - All market segments or classes of trade
 - Internet
 - Secondary sales of contracted pharmaceuticals
 - Pharmacy employees, patients themselves, pharmacists
 - Money
 - Unlawful use



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Excerpt from DEA Letter 12/27/2007

- Distributors are required to:
 - maintain effective controls against diversion
 - report suspicious orders of controlled substances when discovered
 - conduct an independent analysis of suspicious orders prior to completing a sale
 - determine whether controlled substances are likely to be diverted and to take action to prevent the diversion



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10/8

Excerpt from DEA Letter 12/27/2007

- Characteristics of suspicious order
 - deviation in normal pattern
 - significant change in size
 - one product or group of products
 - percentages of purchase mix without validity



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IT Component

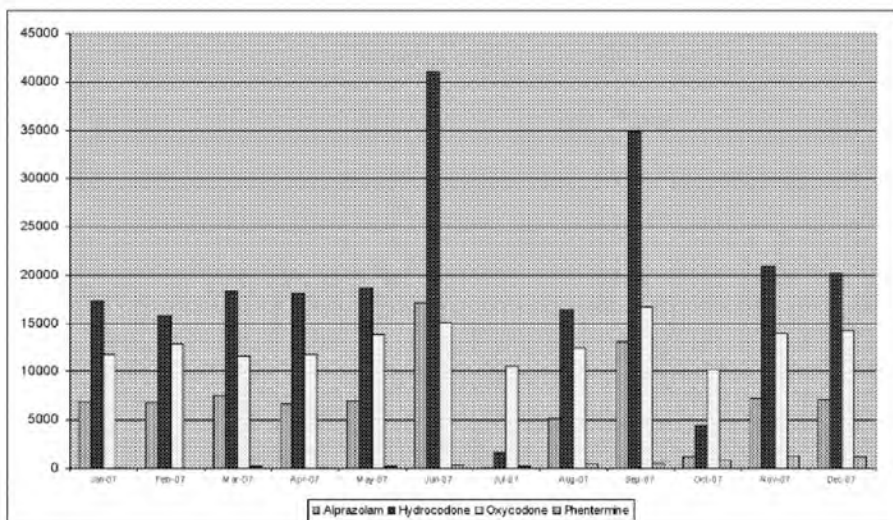
- A tool to assist in our evaluation
- Data mining for patterns and practices
- Continuous review and where appropriate revision of parameters for each customer
 - Increase or decrease
- In future to be used to establish pro-active analysis
- Designed to map purchases to established patterns of valid dispensing



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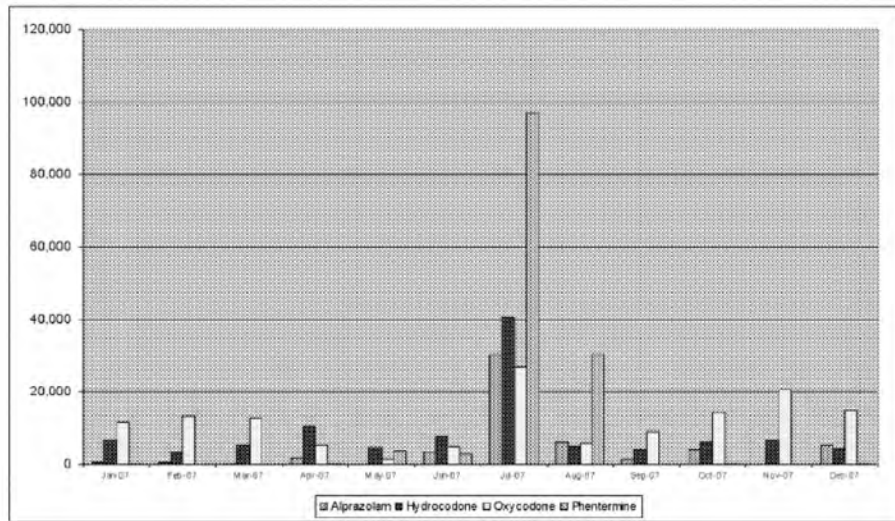
Purchase Data #1



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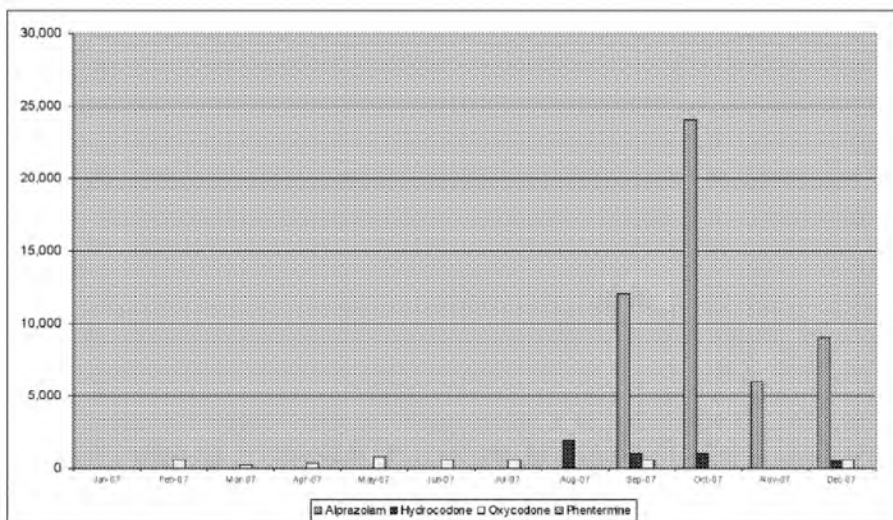
Purchase Data #2



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Purchase Data #3

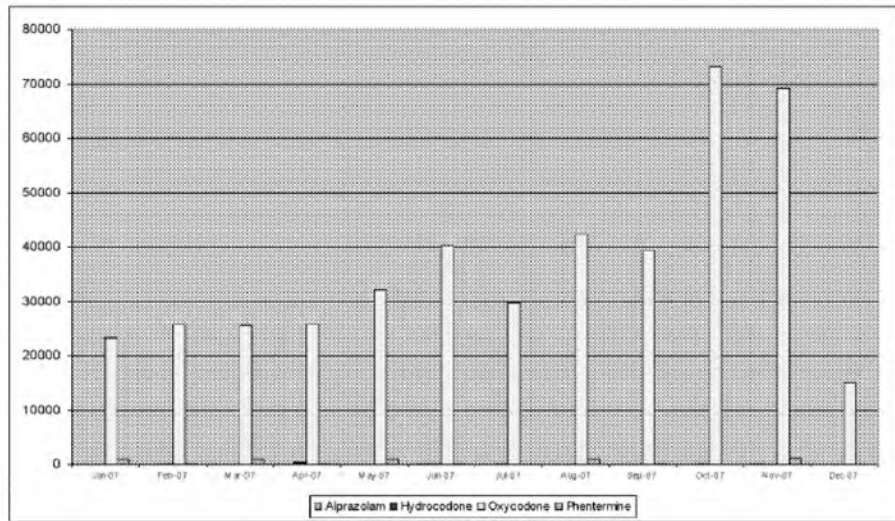


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Purchase Data #4



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Thresholds

- Criteria
 - Class of trade
 - Size
 - Volume
 - Dispensing characteristics
- Categories
 - Small, medium, large, absolute maximum
- Non-discloseable
 - Capture intent



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Thresholds

- Establishment
 - Statistically significant
 - Grouped by active ingredient
 - Standardized customers into cohorts of similarly situated patterns & characteristics
 - Flexibility for customers to order within a range and to permit growth of the pharmacy business with validation



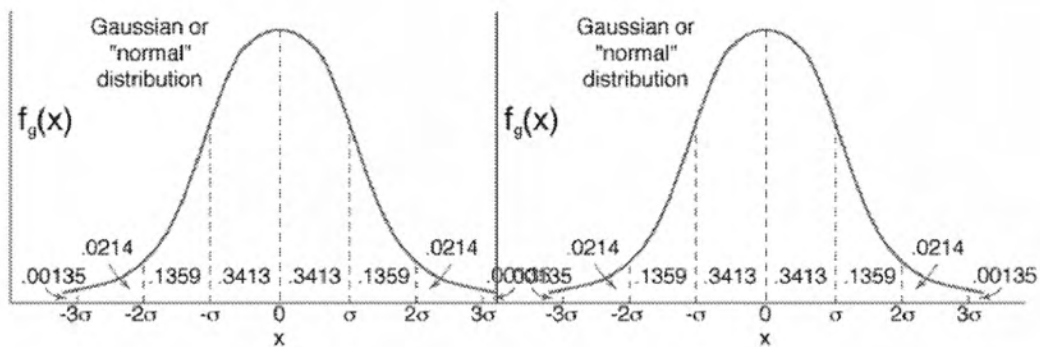
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Thresholds

- Gaussian Distribution



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Thresholds

- Statistically designed to appropriately group similarly situated customers into groups
- Data will drive decisions - if our customers are normal, the number of customers that exceed their initial thresholds should be not more than 2.5% during initial start-up
- Adjustments for QRA thresholds will be both increases and decreases, i.e. customized to the customer
- Based on DEA Certificate of Registration Number



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Thresholds

- “Excess” order or intent to order
 - Held orders – quantity exceeds threshold
 - Invoice informs customer
 - Held Pending Regulatory Review
 - IT component prepares a report of customer patterns and order practices for evaluation
 - QRA Evaluation
 - Turnaround
 - Customer notice
 - Awareness of program
 - Effect on them



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Thresholds

- Cut (Block or Held) Order
 - Subsequent order/intent to order
 - During QRA review of held order
 - Invoice notice
 - Cut Per Regulatory Review
- Prepare our customers for the implementation of this new regulatory environment
- Process developed and implemented simultaneously in a rather aggressive timeframe
 - Program was in the development stages



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QRA Evaluation

- Review of 12 month historical purchases
- Questionnaire sent by Sales Operations to customers to inquire about order – the why
- Questionnaire sent to QRA by customer – the plausibility evaluation
- Verification by site visit
 - Sales
 - QRA



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QRA Evaluation

- Order plausible
 - increase threshold
 - held order released
 - customer may purchase additional quantities
- Order not plausible
 - keep threshold
 - no further orders permitted
 - site visit required



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QRA Evaluation

- Order not plausible and suspicious
 - order blocked
 - suspicious order reported to DEA
 - sales notified
 - customer terminated from purchasing
 - Controlled substances or
 - In totality



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QRA Evaluation

- Balancing of interests based upon available data
- Identify suspicious orders & report to the DEA
 - How much information is available to Cardinal Health?
 - How much responsibility does Cardinal Health have for physician and pharmacy conduct?
- Preserve legitimate business relationships
- Meet legitimate medical/patient requirements
 - We get the right drugs to the right people who administer or dispense the right drugs to the right people who need them.



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QRA Evaluation

- **Risk management**
 - Can Cardinal Health support an account that might be legitimate or might not be legitimate?
 - Does Cardinal Health have to know that the physician / patient relationships are legitimate?
 - Does Cardinal Health have to know that the physician / pharmacy relationships are legitimate?
- **Can Cardinal Health know the answers to these questions?**
- **Cardinal Health must rely in part on regulatory bodies to discharge their societal obligations in a timely manner.**



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12/13

Thresholds

- Phase II
- 101 categories of controlled substances and drug classes
- Some customers will exceed thresholds for several controlled substances and drug families
- Some customers may receive multiple questionnaires, however, if the data is available and validated, adjustments will be made at the initial analysis
 - Sometimes there is no basis in the data with which to justify the change without another questionnaire



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Proactive Threshold Analysis

- Our people
- Know your customer
- Gather information and provide to QRA
 - Significant change in business
 - Hospice contract
 - File purchase of another pharmacy
 - Location change into Medical Center
 - Addition of new Cancer Center



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Retail Independent Process

- Threshold order blocked
- IT report generated
- Threshold order analyzed
- Questionnaire sent
- Questionnaire information validated
- Decision made by QRA
 - Increase
 - No increase
 - Report as suspicious



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Decision Impact

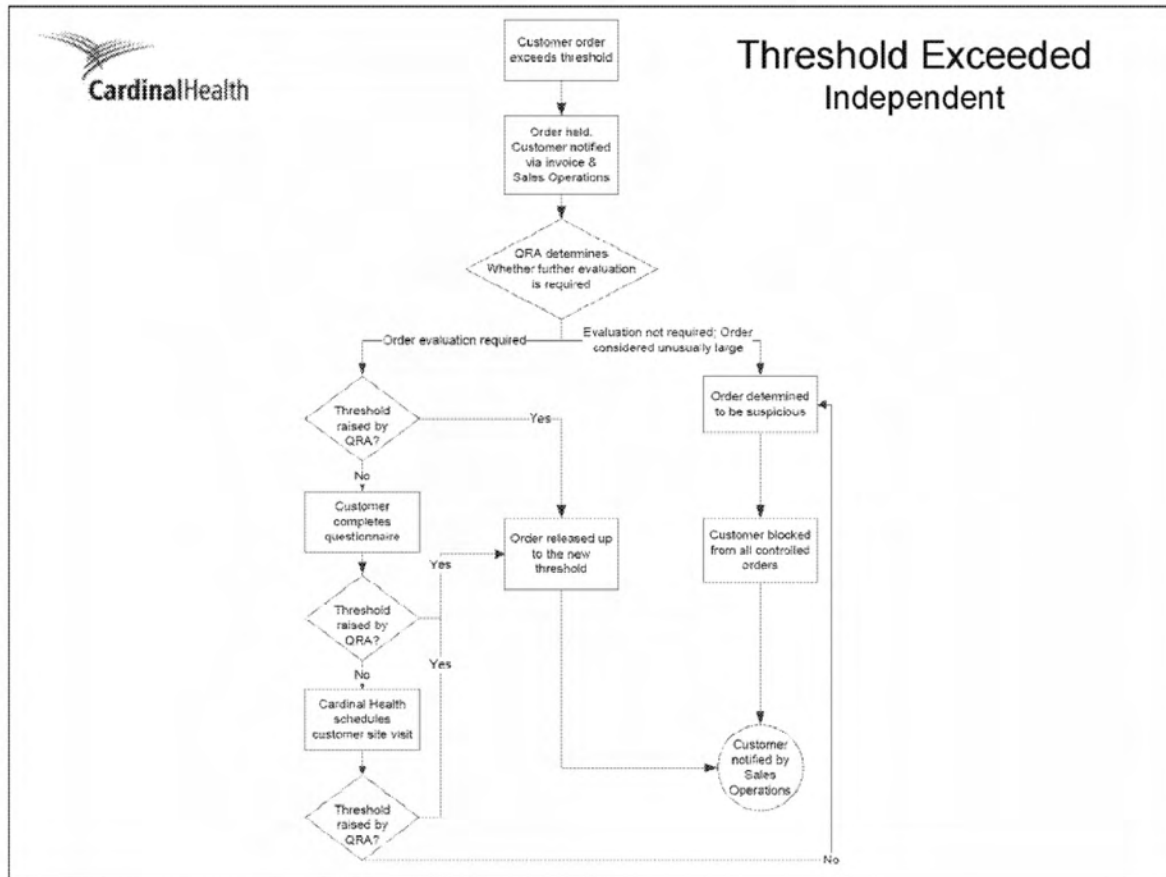
- If the order is justified, additional product from the original order may be released up to the new threshold amount
- If the threshold not is increased, the remaining product from the original order will be cut.
- If the size of the original order is not justified, QRA will send a report to the Drug Enforcement Administration (DEA) and a block will be applied to all families of controlled substances.



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Non Retail Independent Process

- Threshold setting is the same
- Process differs in one respect
- Release of blocked
 - Criticality analysis
 - Likelihood of diversion
 - Existing internal controls and processes to prevent diversion
- Decision same
 - Increase
 - No increase
 - Report as suspicious



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Communication

- The first point of contact for customers should be their sales consultant.
- QRA is developing a SOM searchable information tool to provide an initial place for CAH employees to obtain the current status of the QRA review of blocked orders and threshold determinations
- Sales consultant questions should be directed to GMB-QRA-Anti-Diversion
- Confidentiality can be maintained by contacting www.businessconductline.com or call 800.926.0834



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Case Studies



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Case Study #1

- New Customer Questionnaire
 - Previous pharmacy at the location
 - Change in corporate name
 - Change in DEA Certificate of Registration number
 - Same owners
 - Prior account identified on alert list in 06 and 07
 - ParMed expresses concern about previous pharmacy in August 07
- Questions?



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Case Study #2

- New Customer Questionnaire
 - Previous pharmacy at same location
 - Board of Pharmacy records reflect discipline on owner and pharmacy
 - Change in corporate name
 - Same owners
 - Change in DEA Certificate of Registration Number
 - 75% revenues cash
- Questions?



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Case Study #3

- New Customer Questionnaire
 - Compounding Pharmacy
 - Owner operated a pharmacy at a different location
 - Board of Pharmacy records reflect discipline on owner for Internet dispensing
 - Shipping to 19 states and 2 countries
 - “prescriptions” issued by practitioners not acting in usual course of professional practice
- Questions?



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Case Study #4

- Site visit
 - % controlled substance purchases 30%
 - % HOPA(hydro-oxycodone-phentermine-alprazolam) 61%
 - Disciplinary history of pharmacy and pharmacist
 - Failure to supervise technician – theft of 50,000 du oxycodone for which technician sentenced to 9 years in prison in 2005
 - Prior Internet business – “volume wasn’t high enough” to be in Internet – “mostly non-controlled”
- Questions?



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Case Study #5

- Blocked Order – threshold
 - % controlled substances purchased 23%
 - % HOPA(hydro-oxycodone-phentermine-alprazolam) 70%
 - Hydrocodone threshold 18,000 dosage units per month
 - Alprazolam threshold 7,000 dosage units per month
 - Threshold exceeded for hydrocodone and alprazolam
 - Customer provides data from dispensing software
 - Hydrocodone 18,000 dosage units per month
 - Alprazolam 3,400 dosage units per month
- Questions?



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Case Study #6

- Blocked Order – threshold
 - Small regional chain, 6 stores common ownership
 - Customer hits threshold 1/24 for alprazolam and is adjusted as validated after questionnaire
 - Average purchases of hydrocodone 8,000 dosage units per month
 - Threshold established at 14,000 dosage units per month
 - 12 month historical purchases store never exceeds 14,000
 - No adjustment to hydrocodone
 - Customer hits threshold 1/29 for hydrocodone
- Questions



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Case Study #7

- Site visit analysis
 - Pharmacy in major metropolitan area
 - Underserved community
 - Inquiry by Board of Pharmacy for our records –subpoena
 - % controlled substances purchased 70%
 - % HOPA(hydro-oxycodone-phentermine-alprazolam) 90%
 - Contract between practitioner and patient that prescriptions must be dispensed at this pharmacy
 - 4 Board of Pharmacy disciplinary actions
 - Pain management practitioners: 19 mi; 49mi; 130mi away



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Case Study #7

- Failure to complete DEA 222 Order Forms
- Criminal felony charges of carrying a concealed weapon
- Medical practitioners with disciplinary actions



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Case Study #8

- Site visit
 - 29% Purchases are controlled substances
 - 76% of controlled substance purchases are Hydrocodone, Oxycodone, Alprazolam, & Phentermine

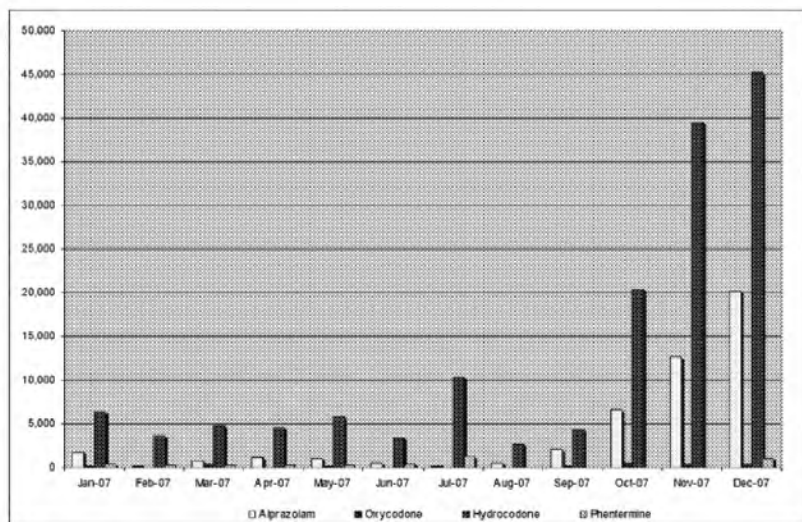


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Case Study #8



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Case Study #9

- Site visit
 - 80% Purchases are controlled substances
 - 77% of controlled substance purchases are Hydrocodone, Oxycodone, Alprazolam, & Phentermine
 - 70,000 phentermine in one month
 - 37,000 phentermine on average per month
- Questions?

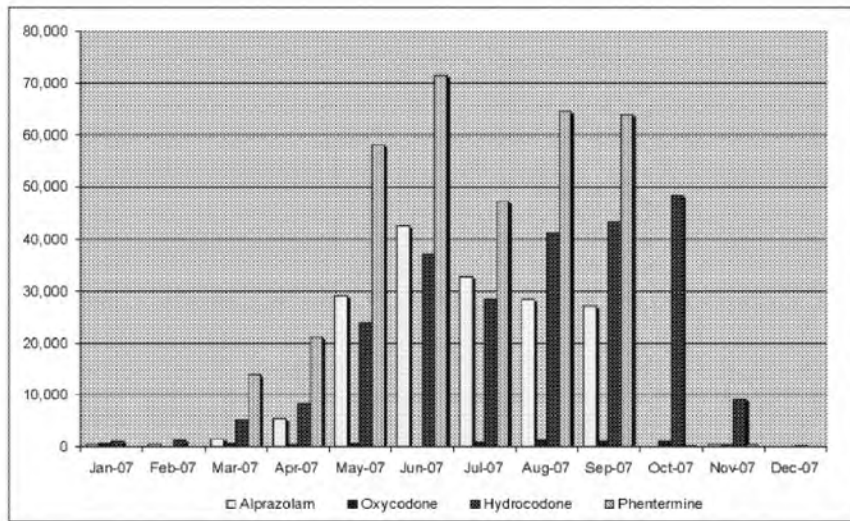


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Case Study #9



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Case Study #10

- Blocked order – threshold
 - Long term care customer – strictly closed door
 - 1 DEA Certificate of Registration Number
 - 6 account numbers
 - 2 coded as 10's – Retail Independent
 - 4 coded as 42's – Managed Care
- Questions?



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Case Study #11

- Blocked Order – thresholds
 - Rural pharmacy in Indiana
 - Somewhat equidistant between Indianapolis and Cincinnati
 - Large purchaser of oxycodone
 - Significant deviation from norms for the size of the pharmacy
 - Pain management practitioners from Indianapolis and Cincinnati
 - Patients are located in zip codes surrounding the pharmacy
- Questions?



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Case Study #12

- Blocked order – threshold
 - Hydrocodone threshold limit 30,000 dosage units per month
 - 1/15 hydrocodone order 336,500 dosage units
 - Blocked order
 - Suspicious?
 - Per se and require report to DEA
 - Order error or intent to order large quantity
 - QRA investigation
 - Data, if exclude RBC order, highest in any one month 18,000 du
- Questions?

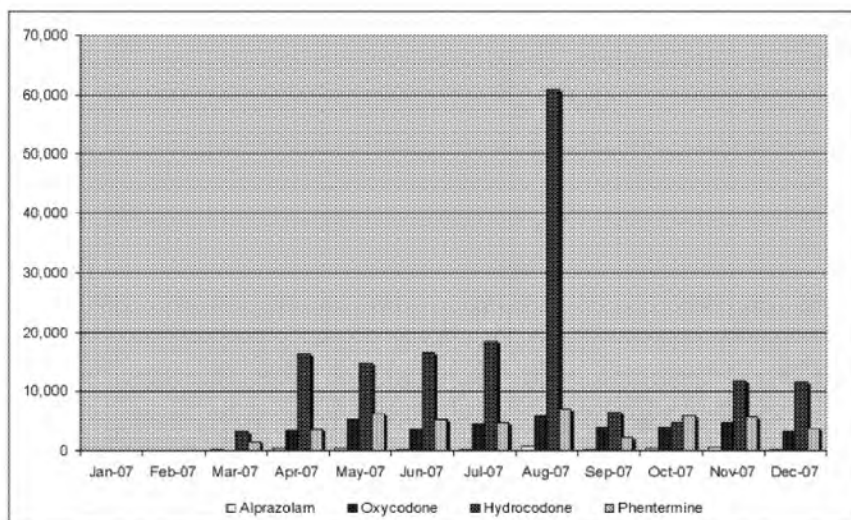


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Case Study #12



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Case Study #13

- Blocked Order – threshold
 - % controlled substances purchased 30%
 - % HOPA(hydro-oxycodone-phentermine-alprazolam) 60%
 - Rural pharmacy
 - Mails 30-40 prescriptions per day to patients
 - Original dispensing at pharmacy
 - Wide service area – 100 mile radius
 - Pain management physicians > 30 miles away
 - On hand quantities 15,000 oxycodone 40mg ER
- Questions?

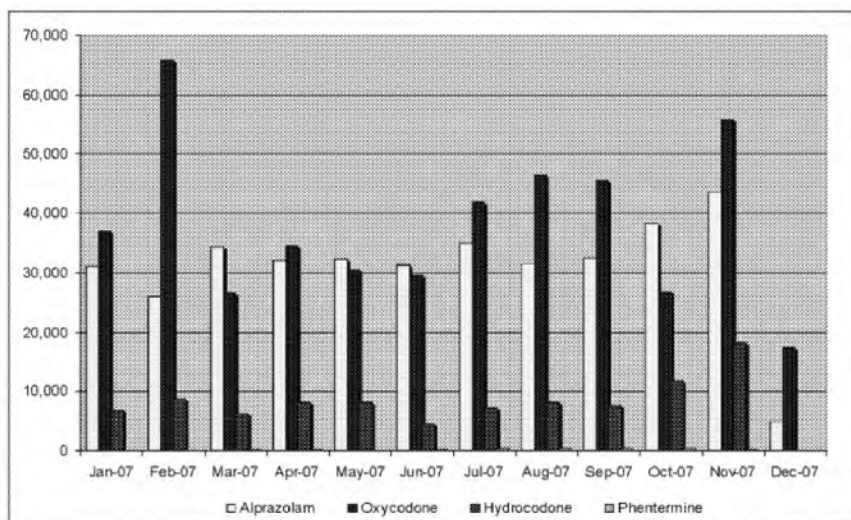


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Case Study #13



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Case Study #14

- Closed customer – sale of pharmacy
 - Customer specifically cited in DEA Order to Show Cause and Suspension Order
 - Account closed
 - Owner is now selling pharmacy
 - Purchaser wants to open account with Cardinal Health
- Issues?
- Questions?

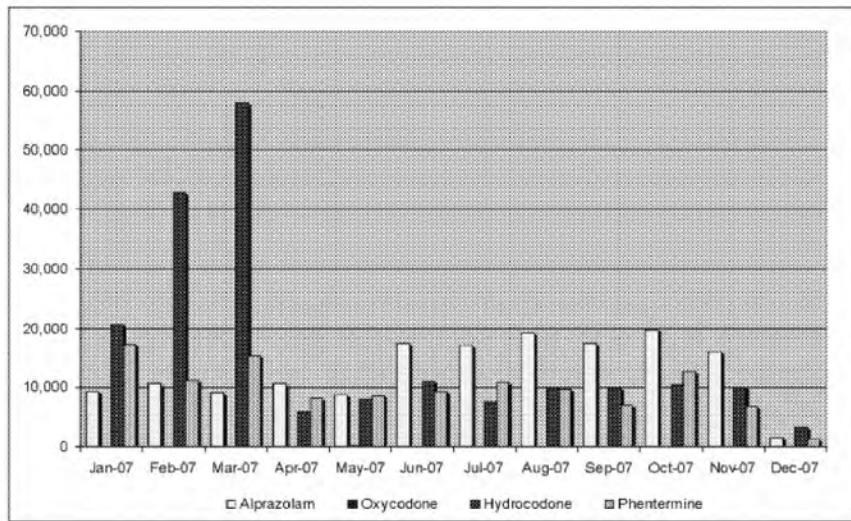


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Case Study #14



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Case Study #15

- Existing customer
 - notice of consolidation of offices
 - 2004 arrest of owner for trading 100 oxycodone and 100 alprazolam for 2 ounces of marijuana
 - License of owner emergency suspended
 - MD's license acted against by Board of Medicine for Internet transactions involving phentermine and Viagra
 - Transition to Jackson of Lakeland customers
 - QRA shuts down ability to purchase
- Questions?

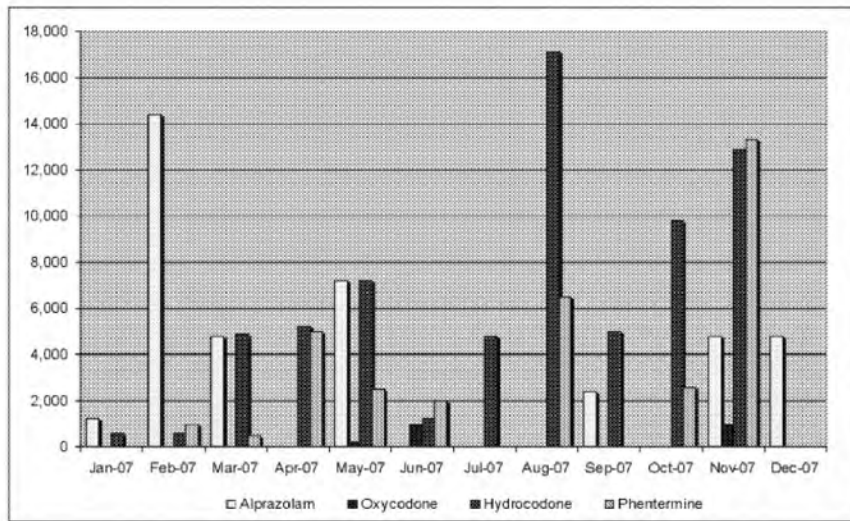


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Case Study #15



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Q&A



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